

## REMARKS

### Replacement Drawings

Replacement drawings are being submitted along with this response to correct errors in the numbering of the elements in the original drawings. The element numbers in the replacement drawings are corrected to correspond to the numbers in the specification. No new matter is included in the replacement drawings.

### Claim Rejections Under 35 U.S.C. §103

Claims 1-3, 9-12, 14 and 15 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 4,562,900 (“Anderson et al.”) in view of U.S. Pat. No. 5,448,994 (“Iinuma”) and further in view of U.S. Pat. No. 4,646,756 (“Watmough et al.”). Claims 4, 6-8, 13, 16, and 18 – 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al., Iinuma, and further in view of Watmough et al. as applied to claims 1 and 9, and further in view of U.S. Pat. No. 5,413,550 (“Castel”). Claims 5 and 17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. in view of Iinuma, and further in view of Watmough et al. as applied to claims 1 and 9, and further in view of U.S. Pat. No. 6,626,855 (“Weng et al.”). Claims 21-27 were rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al., in view of Castel, and further in view of Watmough et al. These rejections are respectfully traversed.

Anderson et al. was cited as the primary reference in the rejections under 35 U.S.C. 103(a). Inherent in these rejections is an acknowledgement by the Office that Anderson et al. does not anticipate any of the independent claims of the present invention. Applicant agrees that Anderson et al. does not anticipate the present independent claims. However, Applicant disagrees that the secondary references supply the deficiencies of Anderson et al.

Independent claim 1 calls for a plurality of individual ultrasound emitting elements actuatable to emit ultrasound, “whereby the ultrasound energy is focused within tissue of the patient at separate and distinct locations for each individual ultrasound emitting element to form a lesion.” Independent claim 9 calls for the ultrasound emitting elements to be “independently actuatable to emit focused ultrasound energy focused a predetermined distance from the active face and focused at separate and distinct locations for each individual ultrasound transducer element.” Independent claim 21 calls for “focusing the ultrasound energy with the selected one or more of the ultrasound emitting elements so that the ultrasound energy is ... focused at

separate and distinct locations for each individual ultrasound emitting element” The applicant asserts that these elements are missing from the cited art.

The Office Action states that Watmough discloses individual transducer elements focused at separate and distinct locations. The Office Action states that this is so because the transducers in the array in Watmough can be individually adjusted to take account of the density and shape of the area to be treated and because the transducers can be separately motor driven to a particular angle and target. Therefore the Office Action concludes that each ultrasound element is focused at a separate location. The Applicant disagrees with this characterization of Watmough.

Watmough does not teach or suggest that the ultrasound array can produce multiple foci at separate and distinct location. Throughout the specification, Watmough refers to the focus produced by the array in the singular form, as “a focus” or “the focus.” Watmough never refers to more than one focus or foci. For example, see the following locations in the Summary of the Invention of the specification which refer to the focus in the singular form: col. 1, l. 59; col. 1, l. 61; col. 2, l. 7; col. 3, l. 47; and col. 4, l. 7. Similarly each of the claims of Watmough call for an ultrasound acoustic focus. None of the citations provided by the Office Action refer to more than one foci but rather all refer to a single focus. Furthermore, in order to treat multiple locations, Watmough does not describe providing more than one focus but rather describes moving the single focus throughout the tissue, stating “[t]he whole system may be motorized to move the focus throughout the tumor volume.” (col. 2, ll. 6-8, emphasis added) Therefore there is no disclosure of multiple foci in Watmough and Watmough only contemplates the creation of a single focus.

Each of the transducer elements in Watmough do not have separate and distinct foci, as called for in the claims. Rather, each transducer of Watmough provides a beam of energy, with the intersection of the beams creating the focus. This intersection of beams to create a single focus is depicted in Figures 3 and 4. The effect of this intersection of beams to create a focus is also described in the specification as follows:

The sonic beam 12 generated from the transducer 1 is beamed toward the target 3. All six other sonic transducers are also beamed toward the target 3 and the temperature rise occasioned thereby is cumulative. This is best shown in FIG. 4 where the target depth is 5.5 cms and wherein all seven transducers are arranged to have their acoustic focus at 5.5 cms accordingly. It will be seen that a temperature approaching 50° C. occurs only at the point of acoustic focus. (col. 5, ll. 43 – 51, emphasis added)

Therefore, all of the seven transducers are arranged to have their acoustic focus at a particular depth in the target. Watmough does not suggest focusing energy within tissue of a patient at separate and distinct locations as called for by claims 1 and 9.

The Office Action draws a connection between the statement in Watmough that the transducers can be individually adjusted to account for the density and shape of the area treated and the ability of Watmough to change the angle of the transducers. The Office Action states that the transducers “can be individually adjusted to take account [*sic*] the density and shape of the area to be treated. To allow for this, each of the transducers can be separately motor driven to a particular angle and target.” (p. 2 of the Office Action of December 19, 2006) However, such a connection between adjusting the transducers to account for density and shape and the motion of the transducers is not supported by the specification. These are separate features, relating to separate functions.

The portions of the Watmough which discuss adjusting the transducers to account for density and shape are referring specifically to the power which is delivered to the individual transducers. For example, at col. 1, l. 64 – 66 , Watmough states that “the power output of each transducer is individually controlled so that the energy imparted to tumor tissues of varying densities may be more accurately adjusted to prevent damage to adjacent healthy cell.” (emphasis added) Therefore the adjusting of the transducers for density and shape relates to adjusting the power to the transducers and is unrelated to the movement of the transducers.

However, while Watmough discloses that the transducer elements move relative to each other, Watmough does not teach or suggest that they may be individually angled into the tissue to form separate and distinct foci. Rather, Watmough consistently shows the transducer elements angling together to form a single focus. In further support of this, Watmough describes the motion of the transducers as being relative, stating, for example “[a] stepping motor shown generally at 5 in FIG. 2 is associated with each hinge bracket 19 to alter the relative angle of each transducer portion. The stepping motor 5 is also associated with pinion 22 whereby the whole transducer array can be relatively positioned prior to fine ‘tuning’ by relative movement of individual transducer supports 16.” (col. 4, l. 62 – 68, emphasis added) Therefore the motion of each transducer element is not independent, but rather is relative to the other transducers such that the positioning of one depends upon the positioning of the others. This is consistent with the transducers functioning together to form a single focus, where the focus may be adjusted by changing the relative angles of the transducers. Therefore, the teachings of Watmough suggest

that the ability to adjust the angle of the transducer elements is limited to moving the location of the single focus in the tissue where the beams intersect by adjusting the relative angles of the transducers. Nowhere does Watmough teach or suggest that the transducer elements can be independently adjusted to any desired orientation to create separate and distinct foci.

The Office Action particularly notes that Watmough teaches that a concave array or one or more convex transducers may be used to treat a target region at col. 7, ll. 9 – 13 of Watmough. In describing an array of transducers, this portion of Watmough states:

These are shown as a concave array which is focusable but may in some circumstances be a single concave transducer or one or more convex transducers where for example the tumor overlies a particularly sensitive body organ.

Applicant believes that this portion of Watmough merely means that the array may be focusable (concave) or non-focusable (convex). This is supported by the statement above, which contrast the concave array which is described as focusable with the convex transducers. With this teaching, Watmough still does not disclose focusing energy at distinct and separate foci as claimed.

The Applicant therefore asserts that Watmough does not teach or suggest that the individual ultrasound emitting elements emit ultrasound energy which is “focused within tissue of the patient at separate and distinct locations for each individual ultrasound emitting element to form a lesion” as called for in claim 1 or which “emit focused ultrasound energy … focused at separate and distinct locations for each individual ultrasound transducer element” as called for in claim 9. Furthermore, none of the other references cited by the Office Action teach these claim elements. Therefore, because the prior art does not teach or suggest these elements of the claims, the Applicant asserts that the rejection of the claims should be withdrawn.

If the Examiner comes to believe that a telephone conversation may be useful in addressing any remaining open issues in this case, the Examiner is urged to contact the undersigned.

Respectfully submitted,

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